

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**ZYDUS PHARMACEUTICALS (USA) INC.
and CADILA HEALTHCARE LIMITED**

Plaintiffs,

vs.

GILEAD SCIENCES, INC.,

Defendant.

COMPLAINT

Civil Action No. _____

DEMAND FOR A JURY TRIAL

Plaintiffs Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (collectively, “Zydus”), by and through their attorneys, for their complaint against Defendant Gilead Sciences, Inc. (“Gilead”) alleges as follows:

NATURE OF THE ACTION

1. This is a civil antitrust action seeking treble damages arising out of Gilead’s unlawful exclusion of generic competition from the market for FDA-approved ambrisentan oral tablets for the treatment of pulmonary arterial hypertension (“PAH”), a chronic disease affecting the functions of the lungs and heart. Gilead markets ambrisentan under the trade name Letairis[®] (ambrisentan), which is indicated for the treatment of PAH.

2. Zydus develops, manufactures, and sells quality generic pharmaceuticals that are priced substantially below brand-name drugs. Zydus intends to file an abbreviated new drug application (“ANDA”) with FDA, seeking approval to sell a generic ambrisentan drug product in United States. Currently there are no generic alternatives to Letairis[®] (ambrisentan) and thus the product may cost patients thousands of dollars per month and tens of thousands of dollars per year.

3. Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301-392) (“FDCA”), the FDA requires an applicant submitting an ANDA to demonstrate that the proposed generic drug product is bioequivalent to the brand-name reference-listed drug. Zydus must obtain samples of Letairis® (ambrisentan), the brand-name reference-listed drug, to perform bioequivalence testing as a prerequisite to submitting an ANDA to the FDA.

4. Gilead has abused its monopoly power by denying Zydus the ability to purchase samples of Letairis® (ambrisentan) for use in bioequivalence testing, thereby blocking the FDA approval process before it can begin. Gilead is knowingly and unlawfully excluding Zydus and other potential competitors from the market for FDA-approved ambrisentan oral tablets for the treatment of PAH for no legitimate, pro-competitive business purpose. Gilead’s conduct is causing Zydus irreparable harm and injury to its business. Gilead’s conduct harms consumers by forestalling access to lower-priced ambrisentan drug products and raising healthcare costs.

THE PARTIES

5. Zydus Pharmaceuticals (USA) Inc. is a company organized under the laws of the State of New Jersey with its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

6. Cadila Healthcare Limited is an Indian company with its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad – 380015, Gujarat, India.

7. On information and belief, Gilead Sciences, Inc. is a company organized under the laws of the State of Delaware with its principal place of business at 333 Lakeside Drive, Foster City, California.

JURISDICTION AND VENUE

8. This Complaint is filed, and this action instituted, under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover treble damages resulting from Gilead’s violation, as alleged

herein, of Section 2 of the Sherman Act. This Court has subject matter jurisdiction based on 28 U.S.C §§ 1331 and 1337(a), and 15 U.S.C. § 15.

9. Venue is proper in this judicial district under 15 U.S.C. § 22 and 28 U.S.C §§ 1391(b) and (c) because, on information and belief, Gilead transacts business within this district and the interstate trade and commerce described in this Complaint is carried out, in substantial part, in this district.

BACKGROUND

A. Regulatory Structure for Approval of Generic Drugs

10. Under the FDCA, pharmaceutical companies obtain FDA approval to sell a new drug by filing a New Drug Application (“NDA”), which includes specific data concerning the safety and effectiveness of the drug.

11. In 1984, Congress amended the FDCA by enacting the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). This statute is commonly known as the Hatch-Waxman Act.

12. Under the Hatch-Waxman Act, a pharmaceutical manufacturer may seek FDA approval to market a generic version of a previously approved new drug by filing an ANDA, which relies on the scientific findings of safety and effectiveness included in the original NDA for the brand-name reference-listed drug.

13. The ANDA filer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the brand-name reference-listed drug. Bioequivalence means that there is no significant difference in the rate and extent of absorption of the active ingredient between the proposed generic drug and the brand-drug counterpart.

B. Generic Drugs Offer Significant Savings and Take Significant Sales from Brand Name Drugs

14. Drugs proven to meet bioequivalence requirements through *in vivo* (clinical) and/or *in vitro* (laboratory) testing receive an “AB” rating from the FDA, indicating they are therapeutically equivalent to the brand-name reference-listed drug.

15. Typically, manufacturers of AB-rated generic versions of brand-name drugs price their drugs significantly below the brand-name counterparts.

16. Pharmacists may—and, in most states, must—substitute an AB-rated generic version of a drug for the brand-name drug without seeking or obtaining permission from the prescribing doctor.

17. Congress and state legislatures actively encourage generic substitution of brand-name drugs because of the enormous cost savings to purchasers and consumers.

18. Because of the price differential and the substitution laws, AB-rated generic versions are rapidly and substantially substituted for their brand-name counterparts.

19. Generic competition enables the purchase of generic versions of brand-name drugs at substantially lower prices.

20. Before an AB-rated generic enters the market, a brand-name company can charge above-competitive prices without losing all, or a substantial portion, of its brand-name sales. As a result, brand-name drug manufacturers have a very strong incentive to delay the introduction of AB-rated generic competition into the market.

C. Risk Evaluation and Mitigation Strategies

21. Certain brand-named drugs are subject to restrictions on their distribution or use that are implemented as part of FDA-mandated risk management programs known as Risk Evaluation and Mitigations Strategies (“REMS”).

22. Congress recognized that certain REMS programs could be used by brand-name pharmaceutical companies to impede generic competition. Accordingly, Congress included in the Food and Drug Administrative Amendments Act (21 U.S.C. § 355–1) (“FDAAA”) a subsection that explicitly forbids a holder of a REMS-covered drug from using an aspect of the REMS, such as a restrictive distribution program, to block or delay approval of an ANDA. *See* 21 U.S.C. § 355–1(f)(8).

23. The FDA agrees with this Congressional mandate and has publicly stated that it is impermissible to use a REMS program to hinder generic competition.

D. Letairis[®] (ambrisentan) oral tablets

24. Ambrisentan is an endothelin receptor antagonist. Gilead holds approved NDA No. 22-081 for ambrisentan oral tablets and sells its product under the brand name Letairis[®] (ambrisentan).

25. Letairis[®] (ambrisentan) is indicated for the treatment of PAH (WHO—i.e., World Health Organization—Group 1) in patients with WHO Class II or III symptoms to improve exercise capacity and delay clinical worsening.

26. Because Letairis[®] (ambrisentan) can cause serious birth defects if taken during pregnancy, Letairis[®] (ambrisentan) is available to females only through the REMS program called Letairis[®] (ambrisentan) Education and Access Program (“LEAP”), a restricted distribution program that informs physicians and patients about the risks associated with the product and about appropriate use of the product.

27. Letairis[®] (ambrisentan) is distributed exclusively by specialty pharmacies, which dispense medications for certain conditions that require ongoing patient education and counseling. On information and belief, these pharmacies have agreed with Gilead not to supply Letairis[®] (ambrisentan) to any entity not specifically approved by Gilead.

E. Zydus seeks FDA approval to market a generic version of Letairis[®] (ambrisentan)

28. For many years, Zydus has been in the business of developing, testing, manufacturing, and selling lower-priced generic versions of brand-name drugs.

29. Zydus has significant experience developing and safely testing generic drugs for bioequivalence to brand-name drugs. Zydus has demonstrated that it can follow all safety protocols in bioequivalence testing, including safety protocols that assure test subjects are not pregnant.

30. Zydus intends to file an ANDA with the FDA seeking approval to market an AB-rated equivalent to Letairis[®] (ambrisentan).

31. As part of its ANDA, Zydus is required to demonstrate that its proposed ambrisentan product is bioequivalent to FDA-approved Letairis[®] (ambrisentan). FDA regulations specify that bioequivalence must be proven with respect to an FDA-approved “listed drug.” 21 C.F.R. § 314.94(a)(3). Accordingly, Zydus needs access to an amount of Letairis[®] (ambrisentan) sufficient for Zydus to conduct bioequivalence testing,. Letairis[®] (ambrisentan) is an essential facility or resource, access to which is wholly controlled by Gilead.

**F. Gilead’s Anticompetitive Scheme
To Prevent Zydus from Developing Its Product**

32. Zydus attempted to purchase ambrisentan tablets from commercial suppliers but was unable to do so.

33. On information and belief, Letairis[®] (ambrisentan) distributors have not and will not supply samples of Letairis[®] (ambrisentan) to Zydus without Gilead’s approval.

34. On June 16, 2014, Zydus sent a letter to Gilead requesting to purchase Letairis[®] (ambrisentan) for use in bioequivalence testing as part of Zydus’s development of its ambrisentan product to be submitted to the FDA pursuant to an ANDA. Zydus offered to pay

Gilead the wholesale acquisition costs for the samples in addition to any shipping and handling expenses.

35. Zydus informed Gilead that Zydus had made reasonable efforts to obtain samples of Letairis[®] (ambrisentan) from other commercial suppliers but had been unsuccessful.

36. Zydus further informed Gilead that Zydus's storage, handling, and bioequivalence testing would comply with all applicable safety requirements and that Zydus's bioequivalence testing protocols would be consistent with the controls in the Letairis[®] (ambrisentan) REMS program and with the prescribing and dispensing instructions in the approved package insert.

37. Gilead did not respond to Zydus's June 16, 2014 letter.

38. Zydus sent Gilead a follow-up correspondence on July 21, 2014. In that follow-up correspondence, Zydus again explained that: (a) it was seeking to purchase samples for purposes of bioequivalence purposes only; (b) its bioequivalence testing protocols would be consistent with the controls in the Letairis[®] (ambrisentan) REMS and with the prescribing and dispensing instructions in the approved package insert; and (c) it would pay the wholesale acquisition costs for the samples, plus shipping and handling expenses.

39. To date, Gilead has refused to sell samples of Letairis[®] (ambrisentan) to Zydus.

40. Gilead's actions have caused and are directly causing significant delays in Zydus's filing of its ANDA for ambrisentan.

41. Zydus has been and continues to be injured by Gilead's denial of access to Letairis[®] (ambrisentan) samples, which has delayed Zydus's development and testing of ambrisentan and further delayed Zydus' filing of an ANDA for ambrisentan.

42. At all relevant times, Zydus has intended to and currently intends to sell a bioequivalent ambrisentan product. Zydus has extensive experience in developing generic drugs,

possesses the knowledge and experience necessary to complete an approvable ANDA for generic ambrisentan and has the financial capability to develop, manufacture and sell that product.

Zydus has taken affirmative steps towards entry in the market for ambrisentan, including attempting to obtain samples of Letairis[®] (ambrisentan) from Gilead for bioequivalence testing that meets FDA requirements.

43. By refusing to sell samples to Zydus and by refusing to allow its distributors to sell samples to Zydus, Gilead has impeded and delayed Zydus's development of an ambrisentan product. Gilead has impeded and delayed Zydus's filing of an ANDA for ambrisentan.

44. Gilead's misconduct delayed Zydus' development, testing, production and sale of ambrisentan. But for Zydus' wrongful actions, Zydus would have been able to introduce a lower-priced competing ambrisentan product into the market sooner than Zydus can do now.

45. On information and belief, Gilead has knowingly and intentionally engaged in this anticompetitive activity to unlawfully "block or delay approval," 21 U.S.C. § 355-1(f)(8), of an AB-rated generic version of Gilead and to willfully maintain its monopoly power.

46. Gilead's wrongful acts directed at Zydus will have the effect of excluding competition, reducing market output, raising competitors' costs, and keeping the price for FDA-approved ambrisentan above competitive levels, all of which is harmful to consumers.

INTERSTATE COMMERCE

47. Gilead's efforts to monopolize and restrain competition in the market for FDA-approved ambrisentan oral tablets for the treatment of PAH substantially affects interstate and foreign commerce.

48. At all material times, Gilead has manufactured, promoted, distributed, and sold, and continues to manufacture, promote, distribute, and sell, substantial amounts of Letairis[®]

(ambrisentan) in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

49. At all material times, Gilead has transmitted and continues to transmit funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Letairis[®] (ambrisentan).

50. In furtherance of its efforts to monopolize and restrain competition in the market for FDA-approved ambrisentan oral tablets for the treatment of PAH, Gilead uses the United States mail and interstate and international telephone lines as well as means of interstate and international travel.

RELEVANT MARKET AND MONOPOLY POWER

51. The relevant product market in which to analyze the anticompetitive effects of Gilead's unlawful conduct is FDA-approved ambrisentan oral tablets for the treatment of PAH, i.e., Letairis[®] (ambrisentan) and any AB-rated generic equivalents. The relevant geographic market is the United States and its territories.

52. The FDA lists Letairis[®] (ambrisentan) as a new chemical entity. Letairis[®] (ambrisentan) is the only drug product approved for marketing by the FDA that contains ambrisentan.

53. Letairis[®] (ambrisentan) has different ingredients, a different clinical profile and a different mechanism of action than other drugs approved by the FDA to treat PAH.

54. Gilead actively and successfully promotes Letairis[®] (ambrisentan) as a drug highly differentiated in therapeutic attributes from other drugs approved by the FDA to treat PAH.

55. Letairis[®] (ambrisentan) is approved by the FDA to treat PAH with once daily dosing. Unlike most other drug products used to treat PAH, patients taking Letairis[®] (ambrisentan) have to take only one dose per day.

56. The once-daily dosage amount for Letairis[®] (ambrisentan) is 5 mg to 10 mg, which is much lower than the dosages required by most other products used to treat PAH.

57. In 2011, the FDA allowed Gilead to remove liver-related warnings that had been included in the prescribing information for Letairis[®] (ambrisentan).

58. Unlike other drug products used to treat PAH, patients taking Letairis[®] (ambrisentan) do not have to undergo monthly blood tests to monitor liver function.

59. Letairis[®] (ambrisentan) has a side-effect profile that is different from other drug products used to treat PAH.

60. On information and belief, patients with abnormal liver function test results discontinue other PAH treatments in favor of Letairis[®] (ambrisentan).

61. On information and belief, unlike other drug products used to treat PAH, Letairis[®] (ambrisentan) has no clinically relevant interactions with frequently co-administered medications such as sildenafil or tadalafil.

62. Letairis[®] (ambrisentan) interacts with other drugs in a manner different from other drug products used to treat PAH.

63. Letairis[®] (ambrisentan) is not reasonably interchangeable with other drug products used to treat PAH available in the United States. On information and belief, physicians do not view other drugs approved by the FDA to treat PAH as perfect or close substitutes to Letairis[®] (ambrisentan). The determinative factors in prescribing Letairis[®] (ambrisentan) are

efficacy, safety, side-effect profile, tolerability and overall clinical profile, and not price competition from other drugs with different chemical ingredients.

64. Barriers to entering the market for ambrisentan, including the barrier artificially created by Gilead in refusing to sell samples of Letairis[®] (ambrisentan) to generic manufacturers including Zydus, are high.

65. The availability of other FDA-approved drugs to treat PAH has not constrained and does not constrain Gilead's ability to raise and maintain the price of ambrisentan above competitive levels.

66. Through the anticompetitive conduct alleged herein, Gilead was and is able to profitably charge above-competitive, monopoly prices for Letairis[®] (ambrisentan) while at the same time substantially increasing sales. On information and belief, from 2011 through the final quarter of 2013, sales of Letairis[®] (ambrisentan) increased by approximately 86%.

67. On information and belief, Gilead has priced and prices Letairis[®] (ambrisentan) substantially above marginal production costs.

68. Gilead has maintained and continues to maintain monopoly power with respect to ambrisentan sold in the United States.

69. Gilead's market share in the relevant market is and has been 100%.

MARKET EFFECTS

70. Gilead's refusal to sell Letairis[®] (ambrisentan) samples to Zydus so that Zydus can perform bioequivalence testing has the purpose and effect of unreasonably restraining and injuring competition by protecting Letairis[®] (ambrisentan) from generic competition in the relevant market.

71. Gilead's exclusionary conduct has delayed and will delay the sale of generic ambrisentan in the United States and unlawfully enables Gilead to sell Letairis[®] (ambrisentan) at

artificially-inflated, above-competitive prices. But for Gilead's illegal conduct, Zydus would not have been delayed in obtaining approval for and successfully marketing of an AB-rated generic version of Letairis[®] (ambrisentan).

72. Gilead has no legitimate, pro-competitive business purpose for refusing to sell samples of Letairis[®] (ambrisentan) to Zydus.

73. Zydus has been injured in its business and property by reason of Gilead's unlawful exercise of monopoly power, which has unlawfully delayed Zydus's development, testing, application for regulatory approval and entry into the market for ambrisentan. As a result, purchasers of ambrisentan tablets will have to pay higher prices than they would have to pay in the absence of Gilead's illegal conduct. Zydus's injury is of the type the antitrust laws were designed to prevent and flows from that which makes Gilead's conduct unlawful.

**Count 1: Monopolization and Attempted Monopolization
in Violation of Section 2 of the Sherman Act**

74. Zydus repeats and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

75. Gilead has used and continues to use willful and exclusionary means to improperly maintain and extend its monopoly power in the ambrisentan market, as detailed above.

76. In order to obtain FDA approval of a generic ambrisentan drug product, a generic manufacturer and potential entrant such as Zydus must have access to FDA-approved Letairis[®] (ambrisentan) for bioequivalence testing.

77. Gilead has complete control over Letairis[®] (ambrisentan) samples, which are an essential facility or resource necessary for the production of ambrisentan. By denying Zydus

access to samples of Letairis[®] (ambrisentan), Gilead has intentionally and wrongfully excluded Zydus from, and maintained its monopoly power in, the relevant market.

78. Zydus cannot practically or reasonably duplicate samples of Letairis[®] (ambrisentan) for the purpose of conducting necessary bioequivalence testing. Nor can Zydus obtain samples of the FDA-approved version of Letairis[®] (ambrisentan) from other sources, such as wholesalers, distributors and specialty pharmacies. The only remaining, practical and feasible option available to Zydus is to obtain Letairis[®] (ambrisentan) samples directly from Gilead. Zydus has offered to purchase Letairis[®] (ambrisentan) samples from Gilead at prices that would have been profitable for Gilead to sell the product.

79. Zydus has committed in writing to implementing the safety protocols set forth in the REMS for Letairis[®] (ambrisentan).

80. Gilead has no legitimate, pro-competitive business purpose for refusing to sell samples of Letairis[®] (ambrisentan) to Zydus.

81. The goal, purpose, and effect of Gilead's anticompetitive conduct is to prevent, delay, and/or impede the successful entry of a competitor that would sell ambrisentan in the United States at prices significantly below Gilead's prices for Letairis[®] (ambrisentan), which would substantially benefit consumers by increasing output, creating price competition in the market for ambrisentan and lowering prices paid by the majority of consumers for the drug.

82. The goal, purpose, and effect of Gilead's anticompetitive conduct is also to maintain and extend its monopoly power over ambrisentan and to preserve its monopoly profits. Gilead's anticompetitive conduct to prevent, delay, and/or minimize the successful introduction into the United States marketplace of any generic version of Letairis[®] (ambrisentan) enables

Gilead to continue charging high, above-competitive prices for Letairis[®] (ambrisentan) without a substantial loss of sales.

83. But for Gilead's illegal conduct, Zydus would have begun developing, testing and ultimately marketing ambrisentan well before it actually will do so.

84. But for Gilead's illegal conduct, prescribers, purchasers, and consumers would have substituted lower-priced generic ambrisentan for the higher-priced brand-name Letairis[®] (ambrisentan) well before they actually will do so.

85. Gilead's unlawful monopolization and attempted monopolization has had the following anticompetitive effects:

- i. Competition in the manufacture, sale, and distribution of ambrisentan is restrained, suppressed, and eliminated;
- ii. Gilead has sold and will continue to sell Letairis[®] (ambrisentan) at artificially high, above-competitive prices, reaping monopolist's profits; and
- iii. Deprived of the benefits of free and open competition from FDA-approved generic ambrisentan, purchasers of Letairis[®] (ambrisentan) have been and will continue to be forced to pay artificially high, monopolist's prices for ambrisentan.

86. Gilead's unlawful monopolization and attempted monopolization have unlawfully excluded Zydus from the market for ambrisentan.

87. Zydus has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities as a result of Gilead's unlawful actions. Zydus's injuries are the type that antitrust laws are intended to prohibit and constitute antitrust injuries.

88. Zydus has suffered damages in an amount to be proven at trial.

89. Gilead's refusal to sell samples to Zydus is an act of monopolization undertaken with the specific intent to monopolize the market for FDA-approved ambrisentan oral tablets for the treatment of PAH in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

**Count 2: Monopolization and Attempted Monopolization
in Violation of New Jersey Antitrust Act, N.J. Stat. § 56:9-4**

90. Zydus repeats and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

91. Gilead has used and continues to use willful and exclusionary means to improperly maintain and extend its monopoly power in the ambrisentan market, as detailed above.

92. In order to obtain FDA approval of a generic ambrisentan drug product, a generic entrant must have access to FDA-approved Letairis[®] (ambrisentan) for bioequivalence testing.

93. Gilead has complete control over Letairis[®] (ambrisentan) samples, which are an essential facility or resource necessary for the production of ambrisentan. By denying Zydus access to samples of Letairis[®] (ambrisentan), Gilead has intentionally and wrongfully excluded Zydus from, and maintained its monopoly power in, the relevant market.

94. Zydus cannot practically or reasonably duplicate samples of Letairis[®] (ambrisentan) for the purpose of conducting necessary bioequivalence testing. Nor can Zydus obtain samples of the FDA-approved version of Letairis[®] (ambrisentan) from other sources, such as wholesalers and distributors. Finally, it is feasible for Zydus to obtain Letairis[®] (ambrisentan) samples from Gilead; and Zydus has offered to purchase such samples from Gilead at prices that would have been profitable for Gilead.

95. Zydus has committed in writing to implementing the protocols set forth in the REMS for Letairis[®] (ambrisentan).

96. Gilead has no legitimate, pro-competitive business purpose for refusing to sell samples of Letairis[®] (ambrisentan) to Zydus.

97. The goal, purpose, and effect of Gilead's anticompetitive conduct is to prevent, delay, and/or impede the successful entry of a competitor who would sell ambrisentan in the United States at prices significantly below Gilead's prices for Letairis[®] (ambrisentan), which would effectively cause the price of ambrisentan to decline dramatically.

98. The goal, purpose, and effect of Gilead's anticompetitive conduct is also to maintain and extend its monopoly power with respect to ambrisentan. Gilead's anticompetitive conduct to prevent, delay, and/or minimize the successful introduction into the United States marketplace of any generic version of Letairis[®] (ambrisentan) enables Gilead to continue charging above-competitive prices for Letairis[®] (ambrisentan) without a substantial loss of sales.

99. But for Gilead's illegal conduct, Zydus could have begun marketing ambrisentan well before it actually will do so.

100. But for Gilead's illegal conduct, prescribers, purchasers, and consumers would have substituted lower-priced generic ambrisentan for the higher-priced brand-name Letairis[®] (ambrisentan) well before they will actually do so.

101. Gilead's unlawful monopolization and attempted monopolization as set forth above has had the following anticompetitive effects:

- i. Competition in the manufacture, sale, and distribution of ambrisentan is restrained, suppressed, and eliminated;
- ii. Gilead has sold and will continue to sell Letairis[®] (ambrisentan) at artificially high, non-competitive prices, reaping monopolist's profits; and
- iii. Deprived of the benefits of free and open competition from FDA-approved

generic ambrisentan, purchasers of Letairis[®] (ambrisentan) have been and will continue to be forced to pay artificially high, monopolist's prices for ambrisentan.

102. Gilead's unlawful monopolization and attempted monopolization have unlawfully excluded Zydus from the market for ambrisentan.

103. Zydus has suffered, and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities as a result of Gilead's unlawful actions. Zydus's injuries are the type that antitrust laws are intended to prohibit and constitute antitrust injuries.

104. Zydus has suffered damages in an amount to be proven at trial.

105. Gilead's refusal to sell samples to Zydus is an act of monopolization undertaken with the specific intent to monopolize the market for FDA-approved ambrisentan oral tablets for the treatment of PAH in violation of the New Jersey Antitrust Act, N.J. Stat. § 56:9-4.

Count 3: Tortious Interference with an Economic Advantage

106. Zydus repeats and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

107. Zydus has a reasonable expectation of economic advantage from a prospective economic relationship with third parties, including distributors, pharmacies, and individuals suffering from PAH, all of which would purchase generic ambrisentan drug products.

108. Gilead has been aware of Zydus's intention to submit an ANDA to FDA for a generic ambrisentan drug product since at least June 2014. Accordingly, Gilead is aware of Zydus's reasonable expectation of economic advantage from sales of a generic ambrisentan.

109. Gilead has intentionally and maliciously interfered with Zydus's reasonable expectation of economic advantage from sales of a generic ambrisentan drug product by refusing to sell Zydus samples of Letairis[®] (ambrisentan) for bioequivalence testing, which is required to

obtain FDA approval of Zydus's generic ambrisentan drug product. Gilead does not have a legitimate, pro-competitive business purpose for refusing to sell Zydus samples of Letairis[®] (ambrisentan).

110. If Gilead had not interfered, Zydus would not be delayed in developing, manufacturing, and selling its ambrisentan product and would receive the anticipated benefit of sales and profits from entry.

111. Gilead's tortious interference has directly and proximately caused injury to Zydus's business and property, including, but not limited to, lost profits and lost business opportunities.

PRAYER FOR RELIEF

112. WHEREFORE, Zydus respectfully requests the Court to enter judgment against Gilead as follows:

1. Gilead's unlawful conduct be declared, adjudicated, and decreed a violation of the Sherman Act, 15 U.S.C. § 2;
2. Gilead's unlawful conduct be declared, adjudicated, and decreed a violation of the New Jersey Antitrust Act, N.J. Stat. Ann. § 59:9-4;
3. Gilead's unlawful conduct be declared, adjudicated, and decreed a violation of the New Jersey law of tortious interference;
4. Zydus be granted injunctive relief restraining Gilead from limiting distribution of samples of Letairis[®] (ambrisentan) to Zydus and enjoining Gilead to provide samples of Letairis[®] (ambrisentan) to Zydus for use in bioequivalence testing;
5. Zydus recover compensatory damages, including treble damages pursuant to 15 U.S.C. § 15 and N.J. Stat. Ann. § 56:9-12;
6. Zydus be awarded expenses and costs of suit, including reasonable attorney's fees, to

the extent provided by law; and

7. Zydus be awarded such additional relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

113. Pursuant to Fed. R. Civ. P. 38(b), Zydus demands a trial by jury on all issues so triable.

LOCAL RULE 11.2 CERTIFICATION

114. We hereby certify that the matters in controversy in the above-captioned action are not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Respectfully submitted,

Dated: November 11, 2014

/s/Eric I. Abraham

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